UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION **This document relates to**: *Track Three Cases*	**MDL No. 2804** **Case No. 17-md-2804** **Judge Dan Aaron Polster**

MEMORANDUM IN SUPPORT OF DEFENDANTS'MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF DANIEL C. MALONE

I. INTRODUCTION

Daniel C. Malone—a professor in the Department of Pharmacotherapy at the University of Utah—claims that one of his areas of experience is "studying the issue of drug-drug interactions and how to provide useful information to both prescribers and pharmacists to reduce exposure to harmful combination." (An Expert Report for the National Prescription Opiate Litigation (April 15, 2021) ("Malone Report") at 2, attached to the accompanying Declaration of Tara A. Fumerton ("Fumerton Decl.") as Ex. 1.) Venturing far beyond that claimed experience—and his review of approximately two dozen documents over approximately 17 hours—he draws broad and generalized conclusions about what five major retail pharmacy chains supposedly "could have" done with "data available" to them at some unstated point in time to detect undefined "red flags" and circumstances such as "inappropriate use of opiates." (Malone Report at 2–3, 7–8.)

The analysis supporting those sweeping conclusions is brief, devoid of any citation, and based on a methodology charitably described as opaque. Further, Malone could not identify a

single pharmacy anywhere in the country that has ever utilized the system he claims Defendants[1] should have utilized; nor could he name any other expert or peer in the industry who agrees with him that pharmacies should utilize such systems. Additionally, Malone's conclusions are not supported by reliable data. Despite concluding that each Defendant's system is inadequate, he did not familiarize himself with any of those systems, let alone the technical intricacies and capabilities as would be necessary to opine regarding what Defendants "could have done" at any time in particular, much less at all times over the course of decades. Indeed, he did not even review the correct industry standards for pharmacy claim processing. Neither Malone's Report nor his expected testimony are reliable, and they will be of no help to the jury in this matter. So they fall far short of the gatekeeping standard set by *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 595 (1993). Defendants respectfully move the Court to strike the report and exclude Malone's opinions and testimony at trial.

II. BACKGROUND

Plaintiffs retained Daniel C. Malone to issue an eight-page report in which he purports to analyze seven "key questions," each related to whether it was possible for any or all of the Defendants to use dispensing and related data in certain very specific ways throughout the time period relevant to this litigation. (*See* Malone Report at 2.) Specifically, he sought to address whether it was "possible using data available to chain pharmacy organizations" to:

[1] Defendants are: Walmart Inc. ("Walmart"); CVS Indiana, L.L.C., CVS Rx Services, Inc., CVS Pharmacy, Inc., CVS TN Distribution, L.L.C., and Ohio CVS Stores, L.L.C. (together, "CVS"); Giant Eagle and HBC Service Company (together, "Giant Eagle"); Rite Aid Hdqtrs. Corp., Rite Aid of Ohio, Inc., Rite Aid of Maryland, Inc. d/b/a Rite Aid Mid-Atlantic Customer Support Center and Eckerd Corp. d/b/a Rite Aid Liverpool Distribution Center (together, "Rite Aid"); and Walgreens Boots Alliance, Inc., Walgreen Co. and Walgreen Eastern Co., Inc. (together, "Walgreens").

1. Conduct drug utilization analyses and provide meaningful metrics to assist pharmacists and pharmacy staff to identify and prevent inappropriate use of opiates and other medications both within and across pharmacies within their organization?;

2. Provide pharmacists with alerts/warnings about over-prescribing by certain licensed prescribers?;

3. Detect inappropriate prescribing and consumption using geospatial data analysis?;

4. Detect excessive dose and quantity accounting for prescriber specialty and practice?;

5. Identify potential pharmacy shopping by consumers seeking opiates and other medications?;

6. Identify use of drug combinations, so-called "Holy Trinity", using pharmacy data?; and

7. Detect overuse through early refills or new prescriptions?

(*Id.* at 2–3.)

After a three-page analysis bereft of any citations, Malone concludes that "pharmacy chain organizations created, purchased, or aggregated data that could have been used to reduce the inappropriate use of opiates and other medications." (*Id.* at 7.) Malone has not been qualified to testify as an expert in any capacity in the past. (Transcript of Deposition of Daniel Charles Malone (May 28, 2021) ("Malone Tr.") at 33:19–34:1, Fumerton Decl. Ex. 2.)

A. Malone's Deficient Reliance Materials

The Malone Report does not contain a single footnote, endnote, or inline citation to any source, either public or produced in the course of this litigation. Malone provides a list of about two dozen documents he reviewed (Malone Report at 3–4), but he never explicitly draws upon any of those sources (or indicates the ways in which he has done so). He also was unable to provide any additional clarity at his deposition regarding what documents formed the basis for his opinions in this case. In fact, he testified that he reviewed all of the materials listed in his report in a mere

17 hours. (Malone Tr. 193:12–20.) He received those materials from Plaintiffs' counsel and did not know whether the materials constituted all of the relevant documents he needed to form his opinions. (*Id.* at 25:21–24.)

For example, as to Walmart, Malone indicated that he relied on a scant three documents (the most recent of which was dated 2012), and he testified at his deposition that he did not "know what other documents Walmart has generated since 2012 that would be relevant to this case," nor did he ask to review any other information before rendering his broad opinions regarding the capabilities of Walmart's systems. (Malone Report at 3; Malone Tr. at 184:5–190:3.) He added, "That is information I don't have at my disposal. I only know what was provided to me [by Plaintiffs' counsel]." (*Id.*)

Notably, the list of materials Malone claims to have relied on does not include a single document purporting to show the technical specifications—over time or at all—of any Defendant's pharmacy software or data science capabilities. To take Walmart as an example once again, the three documents Malone was given and reviewed were (1) a user manual for Connexus[2] from 2009, (2) a user manual for Connexus from 2010, and (3) a PowerPoint related to the Connexus software dated 2012. (Malone Report at 3.) Malone also testified that he reviewed the transcript of Walmart 30(b)(6) designee Darren Townzen's deposition and some undisclosed number of exhibits to that deposition, although the exhibits are not listed out separately as reliance materials in his report. (Malone Tr. at 186:5–18.) Notably, Townzen did not testify regarding the comprehensive technical specifications applicable to the various software systems that stored

[2] [redacted]

dispensing and related data over the course of the relevant time period in this litigation. Indeed, Malone apparently never attempted to ascertain what information already is available to any Defendant's pharmacists through existing systems. Nor does he appear to have undertaken any effort to understand the technical specifications of any of those systems in a way that would permit him to opine as to whether those systems should—or even could—be altered in the ways he suggests.

Malone also says he reviewed the National Council for Prescription Drug Program's (NCPDP's) technical standard documentation called "Script V5.0" (Malone Report at 4), but when questioned about this during his deposition, he admitted (1) he was "not familiar with the data elements in the latest version of [NCPDP's] claims processing standard" and (2) that his report cited the incorrect standard applicable for data elements relevant to pharmacy claims processing. (Malone Tr. 201:21–205:15, 311:1–312:1.) The fact is that Telecommunications D.0 Standard is the standard for pharmacy claims transactions between pharmacies and third party payors, while the Script V5.0 standard—which Malone claimed to have reviewed—actually is the electronic prescribing standard created to facilitate the transfer of prescription data *between* pharmacies, prescribers, intermediaries, facilities, and payors. He acknowledged that he *should have* cited Telecommunications Standard D.0, but in the next breath admitted, "I am not familiar with D.0." (*Id.* at 311:11–15, 312:1.)

B. Malone's Three-Page "Analysis"

Malone's entire analysis—purporting to cover all five Defendants—comprises fewer than three pages of his report, and does not include a single citation. (*See* Malone Report at 4–7.) Worse, it does not cogently address any of the "key questions" he identifies at the outset of the report. It contains no subsections or other guideposts clarifying which portion of the analysis supposedly addresses which (if any) of the seven questions. Although some concepts associated

with some of the key questions are scattered throughout the analysis, the report does not directly speak to any question (let alone suggest an answer to any question, either as to the Defendants generally, or to any Defendant specifically).

For example, Key Question #2 asks: "[W]as it possible using data available to chain pharmacy organizations to . . . [p]rovide pharmacists with alerts/warnings about over-prescribing by certain licensed prescribers?" (Malone Report at 2.) But the report never revisits the concept of "over-prescribing." (*Id.* at 4–7.) Similarly, Key Question #7 asks: "[W]as it possible using data available to chain pharmacy organizations to . . . [d]etect overuse through early refills or new prescriptions?" (*Id*. at 2.) Yet, the only other time the report makes any reference to early refills is the conclusory statement (with no citation) that "[r]ed flags related to pharmacy shopping, doctor shopping, pattern prescribing, early fills/refills, and frequent cash payment could have been implemented within each organization using available data." (*Id.* at 5.) Malone uses the word "refill" twice more in this section of his report, but not in a manner that even attempts to describe how pharmacies could use early refill data to "detect overuse." Indeed, Malone does not discuss the (undefined) concept of "overuse" at all. (*Id.* at 4–7.) Similar deficiencies plague Malone's "evaluation" of each of the seven questions his report supposedly set out to answer. (*Id.* at 2–3, 4–7.)

Malone also does not explain the methodology he employed when examining the key questions and offering his opinions in this matter. Instead, he draws unsupported conclusions about the capabilities of Defendants' systems. (*See id.* at 4–7.) Malone never explains *how* he knows, for example, that "[e]ach pharmacy organization . . . had a . . . central server or computer system that could have been used to assist pharmacists and pharmacy staff identify [*sic*]

inappropriate opioid use."[3] Indeed, he admitted during his deposition that he was not familiar in any technical respect with any Defendant's computer or back-office systems (with the possible minor and completely unremarkable exception of the one year he worked as a pharmacist for Walgreens in the 1980s). (Malone Tr. 70:12-18.) He further admitted that he had no experience working for a pharmacy organization in any capacity related to data science or utilization. (*Id.* at 71:1–9.)

This is but one example of how Malone's broad conclusions are completely unmoored from the type of information actual experts in his field would use in the course of their non-litigation work. That could be why, as Malone admitted during his deposition, *no actual pharmacy* has ever used data in the way he opines was possible:

> Q: . . . Can you point to any particular pharmacy that has done what you think should have been done in the entire industry?
>
> A: Well, IMS Health provided – whether they have done, implemented it or not is another matter. **I cannot point to a particular pharmacy**.

(Malone Tr. 183:3–8)

> Q: . . . But going back to this dashboard, again, you can't point to any examples of this dashboard ever being utilized in practice that has all of these elements that you describe, correct?
>
> A: That is correct.

(*Id*. at 250:12–24.)

What little information the report does offer is rendered effectively useless by its lack of meaningful definitions of key terms. Although he purports to conclude that Defendants possessed data necessary to "inform pharmacists and pharmacy staff to potential illegitimate opioid use" (Malone Report at 8), Malone never defines exactly what circumstances he believes Defendants

[3] In fact, some Defendants had and used such systems. But the fact Malone happened to speculate correctly on one issue does not render his opinion helpful or reliable.

would have been able to detect. He does not explain what he means by "over-prescribing," "inappropriate prescribing," "inappropriate consumption," or "excessive dose and quantity." He also does not define which "drug combinations" he views as problematic or what he believes constitutes "pharmacy shopping" or "doctor shopping." These deficiencies make it difficult to determine what Malone's final conclusions even are.

In sum, Malone's report is based on scant information, never actually answers any of the questions it purports to address, and does not support its conclusions with any particular information, methodology, or expertise.

III. ARGUMENT

A. Legal Standard

Expert evidence "can be both powerful and quite misleading because of the difficulty in evaluating it." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 595 (1993). Federal district courts therefore have been assigned a gatekeeping function to exclude expert evidence that "is unreliable and irrelevant" under Federal Rule of Evidence 702. *Id.* at 597; *Conwood Co., L.P. v. U.S. Tobacco Co.*, 290 F.3d 768, 793 (6th Cir. 2002).

Rule 702 in turn has three requirements: (1) the witness must be **qualified**; (2) the witness' testimony must be **relevant**; and (3) the witness' testimony must be **reliable**. *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008); *Saint Gobain Autover USA, Inc. v. Xinyi Glass N. Am., Inc.*, 666 F. Supp. 2d 820, 830 (N.D. Ohio 2009). These requirements apply to all expert testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999) (stating that Rule 702 makes "no relevant distinction between 'scientific' knowledge and 'technical' or 'other specialized' knowledge").

Rule 702 provides general standards for courts to assess reliability. First, the testimony must be based upon "sufficient facts or data." Fed. R. Evid. 702. Second, the testimony must be

the "product of reliable principles and methods." *Id.* Third, the expert must have "applied the principles and methods reliably to the facts of the case." *Id.* In assessing reliability, courts in this Circuit can rely upon any number of the non-exhaustive list of factors identified by the Supreme Court in *Daubert*, including: (1) whether a theory or technique has been or can be tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error of the method used and existence and maintenance of standards controlling the technique's operation; and (4) whether the theory or method has been generally accepted by the scientific community. *United States v. Langan*, 263 F.3d 613, 621 (6th Cir. 2001) (citing *Daubert*, 509 U.S. at 593–94); *see also Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001) (providing that the *Daubert* factors will often be appropriate in determining reliability). In *Kumho Tire*, the Supreme Court concluded that a flexible application of the *Daubert* factors is also "useful in scrutinizing non-scientific expertise." *United States v. Mallory*, 902 F.3d 584, 593 (6th Cir. 2018) (citing *Kumho Tire*, 526 U.S. at 149–51).

The general gatekeeping obligation set forth in *Daubert* applies when considering all expert testimony, including testimony based on technical and other specialized knowledge. *Clay v. Ford Motor Co.*, 215 F.3d 663, 667 (6th Cir. 2000) (citing *Kumho Tire*, 526 U.S. at 141). District courts have "considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Madej v. Maiden*, 951 F.3d 364, 374 (6th Cir.), cert. denied, 141 S. Ct. 612, 208 L. Ed. 2d 202 (2020) (citing *Kumho Tire*, 526 U.S. at 152). A district court is not required to admit expert testimony "that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Nelson*, 243 F.3d at 254. The Court also must exercise its discretion to determine "whether the testimony will assist the fact-finder" in deciding the issues

presented. *Fox v. Van Dorn Demag Corp.*, No. 5:08 CV 1668, 2009 WL 10689996, at *2 (N.D. Ohio Sept. 8, 2009).

B. Analysis

The *Daubert* gatekeeping standard exists, in part, to avoid attaching the imprimatur of "expert testimony" to statements that are unreliable. This Court should exclude Malone's opinions and any purported expert testimony at trial in this matter because neither satisfies the Rule 702 standard for reliability.

1. Malone Does Not Support His Opinion With Reliable Sources.

Malone's opinion that "pharmacy chain organizations created, purchased, or aggregated data that could have been used to reduce the inappropriate use of opiates and other medications" is *not* "based on sufficient facts or data." Fed. R. Evid. 702. Malone testified that he reviewed only the handful of outdated documents that counsel for Plaintiffs provided to him, listed in his Report at pages three to four. (Malone Tr. 188:4–11.) As to each Defendant, those documents include only a vanishingly small percentage of the millions of pages produced in this matter, and Malone admittedly made no effort to determine whether any other relevant information existed that might be relevant to the "key questions" he was tasked with answering. Worse, the information Malone reviewed included none of the most basic information that actual experts in the field would use to render opinions about the technical capacities of pharmacy chains. *Kumho Tire*, 526 U.S. at 151 ("Likewise, it will at times be useful to ask even of a witness whose expertise is based purely on experience . . . whether his preparation is of a kind that others in the field would recognize as acceptable.")

2. Malone's Methodology Is Not Discernable, Much Less Reliable.

As noted above, the three-page Evaluation section of the Malone Report contains no citations to any specific sources, making it impossible to discern the basis for his ultimate

conclusions. Malone also provides no insight whatsoever into his methodology or principles for assessing Defendants' use of data. Taken together, these two facts render his opinion inadmissible under Rule 702. Because he offers no explanation of his methods, neither Defendants nor this Court can assess, for example, whether those methods are capable of being tested or ever have been subject to peer review. *See Langan*, 263 F.3d at 621. At a minimum, an expert's opinion must rest on a foundation of more than "subjective belief or unsupported speculation." *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 670 (6th Cir. 2010) (quoting *Daubert*, 509 U.S. at 590).

Malone seems to conclude that each Defendant could have been answering his "key questions" using its dispensing and related data from 2006 through 2018 by analyzing vague categories of data in some unspecified way. He cannot and does not say how he knows this. He does not cite to any document, any schematic, or any description of software ever used by any party in support of this conclusion. Moreover, although he says it "would have been easy" for Defendants to implement the dashboard he suggests was needed, he cannot point to a single pharmacy anywhere in the country that ever did so or to any DEA or Ohio Board of Pharmacy rules, regulations, or guidance suggesting that such a dashboard was required. Thus, there is nothing in his report or his testimony to suggest that his conclusion is based on anything other than "subjective belief or unsupported speculation." *Finn v. Warren County, Kentucky*, 768 F.3d 441, 452 n.1 (6th Cir. 2014). Malone simply guesses at what data each Defendant kept, guesses at what they did (or could have done) with that data, and then suggests (without definition or support) what conclusions they should have drawn as a result. This sheer conjecture falls far short of the standards in Rule 702. *See Tamraz*, 620 at 670.

3. Malone's Analysis And Conclusions Will Not Assist The Factfinder.

The lack of reliable methodology underlying Malone's opinion means that it cannot possibly be helpful to the jury in resolving this matter. *Fox*, 2009 WL 10689996, at *2. Courts in

this jurisdiction regularly exclude expert testimony from individuals who submit conclusory reports containing similar deficiencies to those present here. For example, in *Brainard v. American Skandia Life Assurance Corp.*, 432 F.3d 655, 664 (6th Cir. 2005), the plaintiffs' "expert employ[ed] broad and dramatic language without substance or analysis." The court concluded that "[g]iven the absence of meaningful analysis or reasoning, the district court acted well within its discretion by discarding" the expert's opinion. *Id.* In *Vaughn v. Konecranes, Inc.*, the Sixth Circuit upheld the district court's decision to exclude opinions and testimony submitted by an otherwise qualified engineer, because that person "list[ed] the documents he reviewed to reach his conclusions, but the report [did] not explain *how* his experience led him to his conclusions." 642 F. App'x 568, 577 (6th Cir. 2016). The district court had noted that "it was unable to determine whether [the expert]'s conclusions are the product of reliable principles and methods or whether he reliably applied the principles and methods of the facts to the case." *Id.* (internal quotation marks omitted).

The same result should follow here. Malone's opinions are not reliable because he has given the Court and Defendants no means to assess its underpinnings. Malone employs unvarnished guesswork and does not substantiate his "findings" with support. The Court must exercise its gatekeeping role to prevent Malone's opinions and expected testimony from reaching the jury in accordance with Rule 702 and the *Daubert* standard.

IV. CONCLUSION

For the reasons set forth above, and based on the entire record in this matter, Defendants respectfully submit that the Court should exclude the opinions and testimony of Plaintiffs' purported expert, Daniel C. Malone.

Dated: July 23, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, this 23rd Day of July 2021, I served a copy of the foregoing via electronic mail on all Track 3 parties, the Court, and Special Master Cohen.

/s/ John M. Majoras
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